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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,830	10/20/2005	Toshimitsu Nakashima	21581-00476-US	4578
30678 7590 02/01/2011 CONNOLLY BOVE LODGE & HUTZ LLP 1875 EYE STREET, N.W. SUITE 1100 WASHINGTON, DC 20006				
EXAMINER				
PROUTY, REBECCA E				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
02/01/2011		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/527,830

Applicant(s)

NAKASHIMA ET AL.

Examiner

Rebecca E. Prouty

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-14 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/6/11 has been entered.

Claims 7, 8, and 15 have been cancelled. Claims 1-6 and 9-14 are still at issue and are present for examination.

Applicants' arguments filed on 1/6/11, have been fully considered and but are not deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 2 and 9-14 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 1/11/08.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satoshi et al. (JP 2001/340078) in view of Naylor et al. (WO 96/25509).

Satoshi et al. describe a process for producing polyester comprising 3HB and 3HH using *Alcaligenes eutrophus* (*Ralstonia eutropha*) using oils or fats as carbon source. Satoshi et al. also describe controlling the molar ratio of 3HH by altering the amount of added oil/fat or fatty acid that is used as a carbon source, the use of coconut oil; palm oil, and palm kernel oil as the oil/fat, a composition of fatty acid comprising 47% lauric acid as a carbon source, the use of microorganisms transformed by a recombination vector that contains the gene of a polyester polymerizing enzyme isolated from *Aeromonas caviae*. Satoshi et al. also states that if the oil/fat is added in a large amount

at one time, the concentration of dissolved enzyme in the culture liquid may be decreased and because fatty acids are cytotoxic and may inhibit growth. Therefore, a method in which the fatty acid is added in divided amounts such that they do not inhibit growth or a method in which they are added continuously to maintain a concentration that does not inhibit growth is preferred. Satoshi et al. do not teach keeping the a constant specific substrate feed rate (i.e., a constant value of fat or oil added per net weight of cells).

Naylor et al. (WO 96/25509) describe a method of producing a PHA comprising culturing *Alcaligenes eutrophus* in which the carbon source is fed gradually to avoid a toxic concentration of substrate and to maintain a constant oil uptake rate (i.e., 0.13g/g of non-PHA cell mass/hr (see page 7). Thus Naylor et al. are in fact maintaining a constant specific substrate feed rate of the carbon source. Naylor et al further teach that phosphorus restriction can be used to increase PHA accumulation (see page 4). Naylor et al. teach that their fermentation conditions produce high yields of PHA.

Therefore, it would have been obvious to one of ordinary skill in the art to apply the carbon source feeding strategy of Naylor of the PHA culture methods of Satoshi et al. in order to increase the yield of PHA.

Applicants argue that the microorganism of Satoshi can produce copolymers from a sole carbon source while the microorganism used in Naylor produces only homopolymers from a sole carbon source. However, this is not persuasive as it is not clear how this is relevant to the instant rejection. The rejection suggests using the carbon source feeding strategy of Naylor et al. in the methods of Satoshi and thus one would clearly expect that this would produce a copolymer as the organisms of Satoshi et al. are disclosed to produce copolymers. The organism used by Satoshi and Naylor is the same organism (*Alcaligenes eutrophus*) except that Satoshi et al. teaches use of a recombinant version thereof, transformed with the PHA polymerase of *Aeromonas caviae*, which modification is understood to provide for the production of 3HB-co-3HH copolymers when cultured with oils or fats as a carbons source. A skilled artisan would clearly understand that the lack of the PHA polymerase of *Aeromonas caviae* would account for the distinction noted by applicants.

Applicants argue that Satoshi et al teach that natural oils and fats are significantly less toxic that fatty acids and thus strict control of natural oils and fats is not essential. However, this is not persuasive as Satoshi teaches that "fats and oils may reduce dissolved oxygen concentration in culture

medium if added in large quantities" (see paragraph [0027]).

Thus Satoshi teaches that both can be problematic even if fatty acids are shown to be more cytotoxic. As such a skilled artisan would have been motivated to control the addition of natural oils and fats as suggested.

Applicants further argue that Naylor et al, teaches control of the addition of carbon source relative to the amount of culture medium which is distinct from the specific substrate feed rate as defined in the instant specification which is based on the amount of carbon source in relation to the net weight of cells. However, applicants are incorrect. Naylor teach feeding rape seed oil to achieve a constant oil uptake rate (i.e., 0.13g/g of non-PHA cell mass/hr (see page 7)). Although a skilled artisan would understand uptake rate and specific substrate feed rate to be different things, while Naylor et al. recite that the substrate was fed to achieve an average oil uptake ratio, Naylor et al. clearly did this by assuming that uptake rate can be equated to non-PHA cell mass as they did not in fact do anything to measure uptake rate. Naylor simply fed substrate at the rate of 0.13g of substrate per gram of non-PHA cell mass. Thus Naylor et al. did in fact keep a constant specific substrate feed rate of carbon source as defined in the specification.

Applicants argue that the art does not teach controlling the monomer ratio of the copolyesters by the cited method. However, this is not persuasive as it is not necessary for a finding of obviousness that the modification of the prior art be made for the same reasons as applicants reasons. All that is necessary is that the art provide a reason to make the necessary modification to arrive at the claimed methods not that the reason be identical to that of applicants. (see MPEP 2144). The avoidance of toxicity clearly provides a skilled artisan the needed reason to make the necessary modification particularly in view of the teaching of Satoshi et al. that such toxicity is a potential problem within the methods taught by Satoshi et al. as well.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached at (571) 272-0956. The fax phone number for this Group is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652